

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/421,629 10/19/99 SHORT

J DIVER1260-3

HM12/0514

EXAMINER

LISA A HAILE
GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1600
SAN DIEGO CA 92121-2189

NASHED, N

ART UNIT	PAPER NUMBER
----------	--------------

1652

6

DATE MAILED:

05/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/421,629	App. Ent(s) Short et al.
Examiner Nashaat T. Nashed	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Feb 21, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 32-47 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 32-47 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) Other: _____

The application has been amended as requested in the communication filed December 28, 1999 and February 21, 2001. Accordingly, claims 32-47 have been entered and under consideration in this Office action.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it does not contain the claimed priority information.

The drawings are objected to because of the defects noted on the attached PTO-498. Correction is required.

Claims 32-47 drawn to gene expression library which contains partial or complete metabolic pathway is not enabled in the parent applications serial numbers 08/503,606 and 08/568,994 from which serial number 08/988,224 is a continuation in part. The instant application is a continuation of 08/988,224 and not a divisional application. Since claims 32-33, and 36-47 are not limited to specified enzymatic activities, the claims encompass gene clusters of metabolic pathway which have the priority date of June 3, 1996.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,958,672 (672). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application drawn to the same method claimed in the 672. The claims of the instant application are narrower in scope than those of the 672 patent because claim 32 of the instant application from which all other claims are dependent limits the method to a library constructed either by amplifying the copy number of the DNA population or recovering the DNA and normalizing the representation of various DNAs.

Claims 32-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,168,919 (919). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application drawn to the same method claimed in the 919. The claims of the instant application are narrower in scope than those of the 672 patent because claim 32 of the instant application from which all other claims are dependent limits the method to a library constructed by either amplifying the copy number of the DNA population or recovering the DNA and normalizing the representation of various DNAs.

Claims 32-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,174,673 (673). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application drawn to the same method claimed in the 673 patent. Claim 32 of the instant application from which all other claims are dependent drawn to a method of identifying a protein having a desired activity and limiting the method to a library constructed by either amplifying the copy number of the DNA population or recovering the DNA and normalizing the representation of various DNAs and the library can be screened by any method. In contrast, the method in the 673 patent does not limit the method of constructing the library, but limit the method of screening the library to specific fluorescence method.

Claims 32-47 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims 66-71 and 74-85, 89, 90, 92 and 93 of copending Application No. 08/988,224 (224). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming an obvious variant of the same method. The claims of the 224 application are not limited to a particular method of constructing the genomic or cDNA library, whereas the claims in the instant application are limited the method to a library constructed by either amplifying the copy number of the DNA population or recovering the

DNA and normalizing the representation of various DNAs and the library can be screened by any method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 32-47 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of copending Application No. 09/467,740 (740). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming an obvious variant of the same method. The claims of the 740 application are not limited to a particular method of constructing the genomic or cDNA library, whereas the claims in the instant application are limited the method to a library constructed by either amplifying the copy number of the DNA population or recovering the DNA and normalizing the representation of various DNAs and the library can be screened by any method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification lacks a sufficient written description of the claimed invention. The claimed method is drawn to a method of identifying a desired protein activity from a cDNA or a genomic library wherein said library is prepared by: (i) amplifying the copy number of the DNA population; and (ii) normalizing the representation of various DNAs within the cDNA or genomic DNA population so as to form a normalized library of cDNA or genomic DNA. The instant application and any of its parent application do not contain no teaching to such a method for preparing the cDNA or genomic libraries. In fact, the phrases "normalized library", "normalizing the representation of various DNA", and amplifying the copy number of the DNA population" do not appear any where in the specification.

Claims 32-47 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) The phrase "DNA so isolated" in claims 32 and 44 renders the claims indefinite. It is not clear which DNA is so isolated. Is it the product of the amplification step or the that isolated from a plurality of donor organisms?.
- (b) The phrase "in the normalized library" in claim 32, last line, renders the claim indefinite. The claim is drawn to a method of screening for an enzymatic activity from a cDNA or genomic library constructed by two method. The first method is to amplify the copy number of a DNA population, whereas the second is to normalize the representation of various DNA within the cDNA or genomic library. Thus, the claim is confusing because it appear that the applicant is intend to screen only the normalized library and not the amplified library.
- (c) The phrase "the process of claim 32" in claims 45-47 renders the claims confusing and indefinite. Claim 32 is drawn to a method and not a process. For examination purposes, it is assumed that the Applicant intended to say "the method of claim 32".
- (d) claims 33-43 are included in this rejection because they are dependent on rejected claims and do not correct the deficiencies of the claim from which they depend.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 32, and 36-44 are rejected under 35 U.S.C. § 102(e) as being anticipated by Thomson *et al.* (IDS paper number 3, reference AD: U. S. P. 5,824,485).

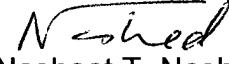
Thomson *et al.* teach method for screening molecular diversity by mixing and cloning genetic material from plurality of species of organism in an amplified combinatorial gene library, see abstract and section 6, column 56 through 62. It should be noted the process of making a cDNA or genomic library involves the biological amplification of the cDNA or genomic DNA (claim 32 and 36-44). They teach that the genetic material can be obtained from any organism including those from environmental samples, plants and marine organisms, see from column 12, line 35 through column 16, line 35. Also, they teach the preparation of the nucleic acid from donor organisms, see column 12, line 35 and section 5.3 starting in column 39, host cells see column 17, line 65, combinatorial expression libraries, see column 25, line 30, screening the combinatorial libraries, see column 32, line 58. Thomson *et al.* specifically teach the isolation of nucleic acid sequence from soil or other mixed environmental samples (uncultured), see section 5.3.6, column 41, protocol for the construction of prokaryotic expression libraries and methods of screening the libraries, in particular for metabolites, see sections 5.4.1-5.4.14, columns 42-50, as well as methods for generating eukaryotic expression libraries using *E. coli*/*S. pombe* shuttle vector which would allow transferring the library from *E. coli* to *S. pombe*, section 5.5, columns 50-55.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday-Thursday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Nashed
Nashaat T. Nashed, Ph. D.
Primary Examiner